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| 10/771,643 | 02/04/2004 | Dale A. Wahlstrom | P-20013.00 | 3719 |

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| EXAMINER | |
|---|---|
| PATEL, JOY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/771,643 | WAHLSTROM ET AL. | |
| | Examiner | Art Unit | |
| | Joy P. Patel | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-37, 41-59* is/are rejected.

7)☒ Claim(s) *10,38-40 and 60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *04 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/4/04 & 6/4/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Elements 381 (See figure 2A) and 311 (See figure 2C). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Specification*

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and

"said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the use of legal phraseology. In line 1 of the abstract, the applicant mentions "Novel retention means..." Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: the word "in tact" on paragraph 17, line 5, should be "intact".

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-3, 6, 8, 9, 25, 30-32 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by Partridge et al. (US 6,842,648).

5. In regard to claim 1, Partridge discloses a lead assembly "...adapted for implantation on or about the heart or within a vein and for connection to a system

for monitoring or stimulating a cardiac activity" (Abstract, lines 1-4). Partridge further discloses, "The electrode assembly includes conductive fixation features, such as conductive tines or flexible members, in combination with non-conductive fixation features." (Abstract, lines 4-6). See also Figure 5, for "retaining segment" 521 and projections 520.

6. In regard to claims 2 and 3, Partridge discloses, "In another embodiment, a lead assembly has a lead body extending from a distal end to a proximal end..." (Column 2, lines 55-57).

7. In regard to claim 6, Conductive tine 520 is an electrode encased in a sheath of conductive polymer (Col.4, lines 26-30)

8. In regard to claims 8 and 9, Partridge discloses, "In one embodiment, the non-conductive tines 340 comprise slender projections which extend away from the lead body 315, for instance, at an angle" (Column 7, lines 40-42). Partridge further discloses, "The tine, in one embodiment, comprises a slender projection which projects from the lead body 215 at an angle of less than 90 degrees" (Column 6, lines 55-58). Since 45 degrees is less than 90 degrees, the tines can be at an angle of approximately 45 degrees.

9. In regard to claim 25, the tines of Partridge are molded (Column 9, lines 25-27)

10. In regard to claim 30, Partridge discloses, "The conductive tine, in one embodiment, includes a conductive coating" (Column 4, lines 46-48).

11. In regard to claims 31 and 32, Partridge discloses, "...the conductive material 1502 comprises...elastomers like conductive silicone rubber and conductive

thermoplastic elastomers like polyurethane elastomers..." (Column 13, lines 20-23).

12. In regard to claim 37, see figure 3, element 320.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 4, 5, 11, 13, 22, 23, 41, 43, 45, and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648) in view of Cates et al. (US 2004/0230282).

14. In regard to claim 4, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that the retaining segments extend about a portion of a circumference of the body. Cates, on the other hand, teaches an implantable lead system that is designed for implantation into a non-thoracic body location, but contains retention means that extend about the entire circumference of the body. Cates discloses, "As illustrated in FIG. 6, one or more ridges 610 may be used in combination with, or

in lieu of, grooves for chronic tissue purchase" (Paragraph 70, Lines1-2; See also figure 6, element 610). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates in order to create a device with projections that would attach to a larger surface area, thereby increasing the resistance to movement.

15. In regard to claim 5, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that the retaining segments extend about the entire circumference of the lead body. Cates, on the other hand, teaches an implantable lead system that is designed for implantation into a non-thoracic body location, but contains retention means that extend about a portion of a circumference of the body. Cates discloses, "The tines 910-960 are also curved around the circumference of the body of the lead 900 with respect to a second plane of reference" (Paragraph 79, lines 8-10; See also Figure 9b). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates, in order to make the lead easier to insert and place in the optimal location.

16. In regard to claims 11 and 52, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that the retaining segments are approximately parallel during insertion and protrude laterally when a retracting force is applied. Cates, on the other

hand, teaches an implantable lead system that is designed for implantation into a non-thoracic body location, but contains retention means that lie approximately parallel during insertion, but then protrude if a retracting force is applied. Cates discloses, "Curvature may assist in acute fixation by providing ease of movement of the lead 800 in a first direction... while helping to set the tines into tissue in response to movement in a second direction."... It is contemplated that the tines may be straight, or have a curvature tending away from or toward the body of the lead 800" (Paragraph 78, lines 12-19; See also figure 8a). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates in order to create a device that was easy to implant, yet difficult to remove.

17. In regard to claims 13 and 45, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that the retaining segments are covered by a thin walled tube covering. Cates, on the other hand, teaches an implantable lead system that is designed for implantation into a non-thoracic body location, but contains a tube covering to go around the retention means. Cates discloses, "Placement of this type of lead fixation may be accomplished by utilization of a sheath, as described earlier, to compress the tines...during placement, and upon removal of the sheath, the tines...spring outwardly from the lead 900 for fixation" (Paragraph 82, lines 6-13). Therefore, it would have been obvious to one of ordinary skill in the art to modify

the device of Partridge in view of the teachings of Cates in order to create a device that was minimally invasive (due to its compressed size) during implantation.

18. In regard to claims 22, 23, 55, and 56, although these references do not disclose the exact length of the retention segment, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates in order to create a retention segment of the appropriate size for the patient that the device is being implanted into. It is known that animals of different sizes have veins of different lengths and therefore, it may require more projections distributed over a larger retention area in order to maintain capture within the vein of some individuals.

19. In regard to claim 41, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that the retaining projections are barb-like. Cates, on the other hand, teaches an implantable lead system that is designed for implantation into a non-thoracic body location, but discloses barb-like projections. Cates discloses, "The barb 1060, similar to a fishhook barb, provides for not only resistance to right to left motion, but also for resistance to further left to right motion after being set" (Paragraph 87, lines 4-7; see also figure 10C). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates in order to create a device that allowed for ease of

insertion in a left to right direction and a resistance to right to left movement (See paragraph 86, lines 8-10).

20. In regard to claim 43, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that the projections are directed toward the proximal end of the retaining segment. Cates, on the other hand, teaches an implantable lead system that is designed for implantation into a non-thoracic body location, but contains projections that are directed toward the proximal end of the retaining segment. Cates discloses, "This complex curvature provides for fixation from both proximal and distal displacement, and from rotation of the lead 900" (Paragraph 82, lines 4-6); See figure 9E. The proximal end of the lead is taken to be the proximal end of the retaining segment. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates in order to minimize displacement and rotation of the lead.

21. In regard to claim 53, see rejections for claims 5 and 52.

22. In regard to claim 54, see rejections for claims 4 and 52.

23. Claims 7 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648) in view of Marshall et al. (US 2001/0044646).

24. In regard to claims 7 and 33-35, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose that the retention means is formed on a collar positioned about the body. Marshall teaches an implantable lead which contains a tine sleeve around the lead. Marshall discloses, "These components together provide a generally rigid assembly, with the tine sleeve 16 fabricated of silicone rubber or relatively softer polyurethanes..." (Paragraph 20, lines 14-16). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Marshall in order to create a stronger, more rigid medical lead.

25. Claims 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648) in view of Peterfeso et al. (US 6,240,322).

26. In regard to claims 12, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that the retaining segments are covered by a dissolvable coating. Peterfeso, on the other hand, teaches an implantable lead system having collapsible tines and a dissolvable coating. Peterfeso discloses, "Alternatively, a bioresorbable material...or other pliable polymer can be used to form the tine" (Column 2, lines 20-21). Therefore, it would have been obvious to modify the device of Partridge

in view of the teachings of Peterfeso, so that the device could have a degradable material that the surrounding tissue would grow around and therefore make the tines more effective in keeping the lead in place.

27. In regard to claim 29, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose information that suggests that tines are embedded in the lead. Peterfeso, on the other hand, teaches an implantable lead system having collapsible tines, which, in one embodiment are embedded in the lead. Peterfeso discloses, "...in one embodiment, the tines 165 have flats 170, which are adapted to be received by each recess 164 (Column 5, lines 18-21; see also figure 3). Lacking any criticality, the use of embedded tines versus tines attached in another fashion would have been an obvious and arbitrary selection to one of ordinary skill in the art of lead construction.

28. Claims 14-18, 46-50, 58, and 59 rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648) in view of Morgan et al. (US 2004/0243210).

29. In regard to claims 14, 16, 18, 46, 48, 50, 58, and 59, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose a preformed curve in the retention segment. Morgan, on the other hand, teaches an intravenous lead having preformed curves near the retention means.

Morgan discloses, "An implantable lead is provided for delivering electrical therapy. The lead, suitable for placement and passive anchoring in a vessel within the coronary sinus region of a patient's heart..." (Abstract, lines 1-4). Morgan further discloses, "...it will be understood by those skilled in the art that the invention is equally applicable to a wide variety of...tissue stimulating leads, including leads having passive fixation tines or fins..." (Paragraph 21, lines 10-14). See also Paragraph 31. From figure 1, it can be seen that there is a bend proximal to the where the retention segment begins (near element 16). Furthermore, it can be seen that there are preformed curves (46) over the length of the retention means with passive fixation texture (64). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge to have curves to further aid in retention, in view of the teachings of Morgan.

30. Claims 15 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648) in view of Morgan et al. (US 2004/0243210) and Alferness et al. (US 5,531,781).

31. In regard to claims 15 and 47, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose preformed curves both proximal and distal to the retention segment. Morgan, on the other hand, teaches preformed curves proximal to the retention means, while Alferness

teaches preformed curves distal to the retention means (see rejections based on Morgan and Alferness). It would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Morgan and Alferness in order to make the lead easier to maneuver into the appropriate vessel, as well as, to aid in keeping the lead in place.

32. Claims 17 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648) in view of Alferness et al. (US 5,531,781). Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose a preformed curve distal to the retention segment. Morgan, on the other hand, teaches an intravenous lead, comprising a preformed curved distal end. From Figure 7, it can be seen that the curved portion 106 is distal to the fixation means 54, which incorporate tines 110, 112, and 114. It would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Alferness in order to construct an intravenous lead that is easy to guide to its proper location within the vessel.

33. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al (US 6,842,648).

34. In regard to claims 19-21, although Partridge does not disclose any size requirements for his lead system, it would have been obvious to one of ordinary

skill in the art to modify the length of the plurality of projections based upon the type and size of animal that it would be implanted into. It is known that larger animals have veins with larger diameters, when compared to those of smaller animals.

35. Claims 24, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648).

36. In regard to claims 24, 26, and 28: Lacking any criticality, the process of creating the plurality of projections through a plasma deposition process, an extrusion process, or a laser ablation process versus any other process would have been an obvious and arbitrary selection to one of ordinary skill in the art of lead construction.

37. Claims 27 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al (US 6,842,648) in view of Carson (US 5,545,206).

38. In regard to claim 27, Partridge as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose a cutting process to create the projections. Carson, on the other hand, teaches a transvenous lead system that consists of tines created by a cutting process. Carson discloses, "The tines 12 are created by cutting slits into the bottom end of the cylinder" (Column 3, lines 44-45). To construct tines for an implantable lead by using a well-known method

of manufacture, such as cutting, would have been obvious to one of ordinary skill in the art.

39. In regard to claim 51, Partridge, as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose a projection containing micro-features to aid in retention. Carson, on the other hand, teaches a transvenous lead system that consists of tines coated with hydrogel on their bottom surfaces (See abstract, lines 10-12) to allow expansion of the tines and therefore provide better retention. Therefore, it would have been obvious to modify the device of Partridge in view of the teachings of Carson in order to create a device that would have a minimum profile during implantation.

40. Claims 36 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al (US 6,842,648). Changing of one type of fixation structure, such as a hair-like projection for another fixation structure, such as a tread-like projection is a mere substitution of known functional equivalents.

41. Claims 44 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge et al. (US 6,842,648) in view of Cates et al. (US 2004/0230282), further in view of Peterfeso et al (US 6,240,322).

42. In regard to claim 44, Partridge as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention

means. However, Partridge fails to disclose a retaining segment comprised of a terminal edge directed toward the proximal end of the retaining segment and a dissolvable coating. Cates, on the other hand, teaches projections that have a terminal end directed toward the proximal end of the retaining segment, but does not disclose a dissolvable coating. Peterfeso teaches projections that are composed of a dissolvable coating. Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates in view of the teachings of Peterfeso, in order to minimize the rotation and displacement of the lead and to allow the surrounding tissue grow around the tines to further minimize rotation and displacement of the lead (See rejections for claims 12 and 43).

43. In regard to claim 57, Partridge as discussed above, discloses an implantable lead, which is suited for implantation into a tubular vessel and contains retention means. However, Partridge fails to disclose a retaining mechanism that allows forward movement, but does not allow backward movement and is comprised of a dissolvable coating. Cates, on the other hand, teaches a medical lead that allows for forward movement, but does not allow for backward movement, but does not teach a dissolvable coating on projections. Peterfeso teaches an implantable medical lead with tines that have a dissolvable coating. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Partridge in view of the teachings of Cates in further view of the teachings of Peterfeso, in order to create a medical lead that would be easy to insert, but

difficult to remove and to allow the surrounding tissue to grow around the tines to further minimize displacement. See rejections for claims 12 and 52 based on Cates and Peterfeso.

**Allowable Subject Matter**

44. Claims 10, 38-40, and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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